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EXAMINER
SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,163	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *119-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *119-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/24/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Part III: Detailed Office Action

Claims 119-131 are pending and under consideration.

Claims are drawn to PRO1111 protein.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

IDS:

The information disclosure statement, filed 5/24/2002, has been considered. The BLAST results demonstrate that applicants are aware of nucleic acids with identity/homology to the one claimed herein. However, as the BLAST results do not give sufficient identifying information, the Examiner cannot determine if said sequences constitute prior art.

Priority Determination:

The utility for the claimed protein is active in a chondrocyte redifferentiation assay. The earliest disclosure of this result that can be confirmed by the Examiner is in US Application 09/941992, filed 8/28/01. It is suspected that priority may exist in PCT/US00/08439. Applicants are requested to provide a copy of that portion of the PCT application which contains the chondrocyte redifferentiation assay in response to this office action to allow a proper priority determination. Accordingly, priority is set at 8/28/2001, with possible priority to 3/3/00, pending review of the PCT application.

It is further noted that applicants may argue that the results of the assay beginning at page 546 of the specification, the delta Ct assay, establish utility and enablement for the claimed invention, resulting in an earlier priority date. That assay is not found to be enabling as required by 35 U.S.C. §112, first paragraph. The results indicate a *mild* amplification in fewer than half the Lung adenocarcinoma, lung squamous cell carcinoma, and colon adenocarcinoma cell lines studied. PRO1111 was found to be amplified approximately two-three fold in 6 of 12 human

lung tumor squamous cell carcinoma cell lines, 4 of 11 human lung tumor adenocarcinoma cell lines, and 4 of 17 colon adenocarcinoma cell lines. The finding that the nucleic acid encoding PRO1111 is amplified, likely indicating aneuploidy, in the aforementioned tumor types is insufficient to confer utility or enablement to the nucleic acid. Cancerous tissue is known to be aneuploid, that is, having an abnormal number of chromosomes (see Sen, 2000, Curr. Opin. Oncol. 12:82-88). The data presented in the specification were not corrected for aneuploidy. A slight amplification of a gene does not necessarily mean overexpression in a cancer tissue, but can merely be an indication that the cancer tissue is aneuploid. The preliminary data were not supported by analysis of mRNA or protein expression, for example. In this case, the sequence of PRO1111 was found at no more than three copies per cell, and only in a minority of tumors tested. The person of ordinary skill in the art would not consider the results to be significant or diagnostic in view of the review by Sen. Further, a search of the art has revealed that J. Wang et al. have reported that the protein encoded by SEQ ID NO: 228 is *downregulated* in brain tumor (see search results for us-09-989-2749-229.rspt, result 1, enclosed). Accordingly, it is not clear whether or not PRO1111 is diagnostic of cancer, or if so which cancers, and the specification does not enable the use of PRO1111 for such diagnosis, and the result from the amplification assay cannot be relied upon to establish a priority date for the nucleic acid. With respect to the claimed protein, even *if* the amplification assay demonstrated utility and enablement of the nucleic acid, it would not do so for the claimed protein. The preliminary data were not supported by analysis of mRNA or protein expression, for example. Thus, the data do not support the implicit assertion that PRO1111 can be used as a cancer diagnostic. Significant further research would have been required of the skilled artisan to determine whether PRO1111 is overexpressed in any cancer to the extent that it could be used as a cancer diagnostic, and thus the implicitly asserted utility is not substantial.

The Examiner's position that an increase in nucleic acid copy number is not predictive of a similar association for protein is supported by the prior art. The art does not recognize that protein levels are increased when gene amplification occurs. For example, Pennica et al., teach that WISP1 and WISP2 are both amplified in tumors, but RNA expression of WISP2 was *reduced* in 79% of tumors, while that of WISP1 was *increased* in 84% of tumors (see abstract). See also Konopka (Proc. Natl. Acad. Sci. (1986) 83:4049-4052), who state that "Protein

expression is not related to amplification of the abl gene but to variation in the level of bcr-abl mRNA produced from a single Ph1 template" (see abstract). Finally, see Haynes et al. (1998, Electrophoresis 19:1862-1871), who studied more than 80 proteins relatively homogeneous in half-life and expression level, and found no strong correlation between protein and transcript level. For some genes, equivalent mRNA levels translated into protein abundances which varied more than 50-fold. Haynes et al. concluded that the protein levels cannot be accurately predicted from the level of the corresponding mRNA transcript (p. 1863, second paragraph, and Figure 1). Therefore, the art indicates that it is not the norm that gene amplification, or increased transcription, results in increased protein levels. Accordingly, the showing that the DNA encoding PRO1111 is present in increased copy number in a particular tumor type would not be sufficient to establish any utility for the protein encoded thereby or antibody that binds to the protein.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to the date recited above which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to that date.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 119-123 and 130-131 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the protein of SEQ ID NO: 229 or fragments of such that are usable for making antibodies or have chondrocyte redifferentiation activity, does not reasonably provide enablement for proteins 80, 85, 90, 95 or 99% identical to such, which do not have chondrocyte redifferentiation activity. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are directed to isolated protein of SEQ ID NO:229 or at least 80% identical to such, fragments, and proteins comprising fragments. The specification contains numerous asserted utilities including use to identify molecules that bind to PRO1111 (including agonists and antagonists), as molecular weight markers, therapeutic agents, and for the production of antibodies. None of these asserted utilities is specific for the disclosed PRO1111 protein, as each of the aforementioned utilities could be asserted for any naturally occurring protein, and further, as none of the asserted utilities requires any feature or activity that is specific to the disclosed PRO1111.

The specification teaches that PRO1111 has (unspecified) homology to proteins having leucine rich repeats, for example see pages 20 and 147. The structure of the putative PRO1111 is said to bear unspecified homology to LIG, but is not otherwise discussed, other than the aforementioned putative two transmembrane domains. There is no disclosure of any extracellular domain.

The sole disclosed utility that is determined by the Examiner to meet the requirements of 35 U.S.C. §101 is the use of the protein in stimulating chondrocyte redifferentiation, for reasons cited above in the priority determination.

The claim encompasses an unreasonable number of inoperative polynucleotides, which the skilled artisan would not know how to use. As opposed to the claims, what is disclosed about PRO1111 is narrow: a single polypeptide with one potential disclosed function and no other obvious specific functions.

There are no working examples of proteins less than 100% identical SEQ ID NO:229. There is but one function potentially attributed to PRO1111 that meets the requirements of 35 U.S.C. §112, first paragraph: stimulation of chondrocyte redifferentiation. While the specification generally describes properties of cytokines, it is acknowledged that cytokines are diverse in function and structure. The specification does not provide guidance for using polypeptides related to (*i.e.,* 80%-99% identity) but not identical to SEQ ID NO:229 which do not have the single specific disclosed activity potentially shown for PRO1111. The claims are broad because they do not require the claimed nucleic acid to encode a polypeptide identical to the disclosed sequence and because the claims have no functional limitation.

For these reasons, which include the complexity and unpredictability of the nature of the invention and art in terms of the diversity of proteins and lack of knowledge about function(s) of encompassed polypeptides structurally related to SEQ ID NO:229, the potential one limited working example of PRO1111 polypeptide and its one function, the lack of direction or guidance for using polypeptides that are not identical to SEQ ID NO:229, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

Claims 119-124, 126-128 and 130-131 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to proteins having at least 80%, 85%, 90%, 95% or 99% sequence identity with a particular disclosed sequence. The claims do not require that the claimed protein possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature The specification teaches that PRO1111 has (unspecified) homology to proteins having leucine rich repeats, for example see pages 19 and 353. The structure of the putative PRO1111 peptide is disclosed as comprising two putative transmembrane domains at page 147 of the specification; however, it is clear from the disclosure that (a) only one of the two, if any, is likely to actually *be* a transmembrane domain, (b) there is

no conception of whether the protein is a type I or type II transmembrane protein, or (c) if it *is* a transmembrane protein, which end of the protein would be the 'extracellular' domain.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, proteins comprising the sequence set forth in SEQ ID NO: 229 or active or antigenic fragments thereof but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear

that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Deposit requirement:

Claims 119-124 and 129-131 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The deposit of biological organisms is considered by the Examiner to be necessary for enablement of the current invention (see 37 C.F.R.§1.808(a)). Examiner acknowledges the deposit of organisms under accession number ATCC 203110 under terms of the Budapest Treaty on International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure in partial compliance with this requirement. However, in order to be fully compliant with the requirement, applicants must state that the deposit will be maintained for a term of at lest 30 years *and at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository*. See 37 C.F.R.§1.806.

Rejections Over Prior Art:

Priority is set at 8/28/2001, but may be granted to 3/3/00. Accordingly, the rejections below are being set forth with each possible priority date in mind.

A search of the nucleic acid sequence databases revealed the following prior art:

Reference	Date	Author	Identity to SEQ ID NO:228
AI769814	12/21/99	NCI-CGAP	100% to bases 1703-2180
AI435407	3/30/99	NCI-CGAP	99.8% to bases 1743-2185
AI470931	4/13/99	NCI-CGAP	100% to bases 1795-2179
T15752	7/25/96	R. Berry et al.	100% to bases 1870-2184
U.S. Patent Number 6,689,866, SEQ ID NO: 9	3/8/00	Shimkets	99.7% to bases 1-2183

U.S. Patent Number 6,689,866, SEQ ID NO: 31	3/8/00	Shimkets	Encodes XC domain, 100% identity to SEQ ID NO : 229, residues 45-492.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 119-123, and 130-131 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Jacobs, WO 99/50405. SEQ ID NO: 2 of the publication is 99.7% identical to SEQ ID NO: 229 of the instant application. Fusion proteins, including to epitope tags, are disclosed at page 54. Accordingly, the claims are anticipated by Jacobs.

Claims 119-124, 127-128, and 132-138 are rejected under 35 U.S.C. 102(e) as being anticipated by Shimkets, U.S. Patent Number 6,689,866 or US Patent Application Publication US2003/0054514 A1, or US Patent Application Publication US2003/0003532 A1. The US Patent Application Publications are divisionals of the patent, and differ only in the claims. The '514 publication contains claims to nucleic acids, proteins (see claim 11), and antibodies (see claim 13), and the '532 application contains claims to nucleic acids and vectors. The teachings will be discussed with reference to the issued patent. SEQ ID NO: 9 of the patent is 99.7% identical to SEQ ID NO: 228 of the instant application, at bases 1-2183 (bases 159-2341 of the patent), and encodes a protein 99.2% identical to that of SEQ ID NO: 229. SEQ ID NO: 31 is a fragment of SEQ ID NO: 9, is identified as encoding the extracellular domain (see figures 17A and 17B), which is 100% identical to residues 45-495 of SEQ ID NO: 229. Fusion proteins, including Ig fusions, are disclosed beginning at column 32, line 50.

Accordingly, the claims are anticipated by Shimkets.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 119-123 and 130 are rejected under 35 U.S.C. 103(a) as being obvious over any one of Loci AI769814, AI435407 , AI470931, or T15752, in view of Sibson et al.

The teachings of the primary references are summarized in the Table above. Each has over 99% identity to SEQ ID NO: 228 over the full length of the locus from the database. As sequence identity is calculated relative to the shorter of the two sequences being compared, the proteins encoded by the sequences would meet the limitations of claims 119-123.

Sibson et al. disclose that it is generally useful to place a desired cDNA sequence into an expression vector, host cell, and express the encoded protein, as well as to raise antibodies to proteins encoded by such cDNA's. See pages 8-13. Fusion proteins are disclosed at page 8 as being useful for purification of the encoded protein.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the DNA's disclosed by any one of the primary references to express and then isolate the encoded polypeptide as taught by Sibson et al. in view of Sibson et al.'s suggestion that it would be desirable to do so, as cited above.

Claim 131 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Loci AI769814, AI435407 , AI470931, or T15752, in view of Sibson et al. and further in view of Capon et al., U.S. Patent Number 5,116,964. The teachings of Loci AI769814, AI435407 ,

AI470931, or T15752, in view of Sibson et al. are discussed above and render obvious the fusion protein of claim 130. However, the cited references do not teach Ig fusions comprising the proteins.

Capon teaches fusion proteins comprising immunoglobulin polypeptides fused to "ligand binding partners", which are defined as including hormones and growth factors (see column 2, lines 14-19). At column 4, lines 38-43, Capon states that the immunoglobulin (Ig) fusions of the invention "serve to prolong the in vivo plasma half-life of the ligand binding partner..." and "facilitate its purification by protein A". Also taught are recombinant materials for making such a fusion protein, vectors and expression; see columns 15-16. Preferred embodiments include sequences including the hinge regions of IgG-1, -2, -3 or -4, IgA, IgE, IgD and IgM, see column 14, lines 40-45 (the first domain of the constant region can be omitted). The preferred species of Ig was human, see claims 8-9. Capon states that the DNA sequences for the Ig chains were well known in the art at the time the invention was made, see column 15 beginning at line 40.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the proteins found obvious above over Loci AI769814, AI435407 , AI470931, or T15752, in view of Sibson et al. to make IgG fusions as taught by Capon et al. The person of ordinary skill in the art would have been motivated to make the modification in view of Capon's disclosure that Ig fusion proteins facilitate purification of desired proteins, which is the same motivation taught by Sibson for making fusion proteins. Accordingly, the invention, taken as a whole, is *prima facie* obvious over the cited prior art.

Advisory Information:

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz. ***Effective 1/21/2004, Dr. Kunz' telephone number is 571-272-0887.***

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
Primary Examiner